

CLAIM AMENDMENTS:

Claims 14-68 were previously withdrawn in a restriction requirement election, and remain withdrawn. Claims 1-13 were rejected. Please amend claims 1, 2, 5, 8 and 12, and further withdraw claims 9 and 13 as follows:

1. (Currently amended) A positive airway pressure (PAP) device for stabilizing breathing during sleep comprising:
a PAP device for sleep therapy, the PAP device further comprising
a source of medical grade carbon dioxide;
an assembly for combining pressurized air from the PAP device with
substantially low concentrations of the medical grade carbon dioxide
resulting in a gas mix; and
a patient centric ventilatory space module (PCVSM) coupled to the
assembly providing the resulting gas mix for inhalation by a given target,
said inhalation of the gas mix effecting respiratory stability of said target.
2. (Currently amended) A device as claimed in Claim 1 wherein the assembly includes a positive airway pressure module for providing the pressurized air a sensor for measuring air flow.
3. (Currently amended) A device as claimed in Claim 1 wherein the PCVSM includes any of:
an incubator, a tent, a facemask, and a nasal cannula.
4. (Original) A device as claimed in Claim 1 wherein concentration of carbon dioxide in the gas mix is less than 2%.

5. (Original) A device as claimed in Claim 1 wherein concentration of carbon dioxide in the gas mix is between about .5% and about 1.25%.
6. (Original) A device as claimed in Claim 1 wherein at least one of the source, the assembly and the PCVSM is computer processor controlled to modulate concentration of carbon dioxide in the gas mix.
7. (Original) A device as claimed in Claim 6 wherein the computer processor modulates concentration of CO₂ in the gas mix as a function of any combination of sensed concentration of carbon dioxide in the PCVSM, sensed target state and detected system changes.
8. (Currently amended) A method for preparing a gas mix for enabling respiratory stability for a positive airway pressure (PAP) device for sleep therapy, comprising the steps of:

providing a substantially low concentration of medical grade carbon dioxide to a PAP device used for sleep therapy; and

combining pressurized air from the PAP device used for sleep therapy with the medical grade carbon dioxide to form a gas mix having stabilizing effects on breathing, the pressurized air enabling the carbon dioxide at low concentrations in the gas mix to have stabilizing effects on target respiratory systems; and

delivering the gas mix to a subject with the PAP device used for sleep therapy.
9. (Withdrawn) The method of Claim 8 wherein the step of combining includes employing positive airway pressure.

10. (Original) The method of Claim 8 wherein the step of combining includes utilizing a face mask worn by a target patient.
11. (Original) The method of Claim 8 wherein the step of providing includes employing carbon dioxide at concentrations of less than 2%.
12. (Original) The method of Claim 8 wherein the step of providing includes employing carbon dioxide at concentrations in the range of about .5% and about 1.25%.
13. (Withdrawn) The gas mix formed by the process of Claim 8.
14. (Withdrawn) A gas modulation system comprising:
 - a source of a first gas;
 - means for mixing the first gas into a gas mix for use in a patient centric ventilatory space module (PCVSM);
 - a sensor, located substantially at the PCVSM, which measures concentration of the first gas in the PCVSM; and
 - a control processor which, based on a signal from the sensor, controls concentration of the first gas in the gas mix.
15. (Withdrawn) The gas modulation system of Claim 14 wherein the PCVSM is any one of an incubator, a tent, a facemask, and a nasal cannula.
16. (Withdrawn) The gas modulation system of Claim 14 wherein the PCVSM is substantially leak-proof.

17. (Withdrawn) The gas modulation system as claimed in Claim 14 wherein the first gas is CO₂.
18. (Withdrawn) The gas modulation system as claimed in Claim 17 wherein pressurized air is a second gas in the gas mix.
19. (Withdrawn) The gas modulation system as claimed in Claim 18 further comprising a positive airway pressure (PAP) module which provides the pressurized air.
20. (Withdrawn) The gas modulation system as claimed in Claim 18 wherein CO₂ in the gas mix is at a substantially low concentration.
21. (Withdrawn) The gas modulation system as claimed in Claim 20 wherein CO₂ is at a concentration below 2%.
22. (Withdrawn) The gas modulation system as claimed in Claim 20 wherein CO₂ is at a concentration in a range of about .5% to about 1.25%.
23. (Withdrawn) The gas modulation system as claimed in Claim 17 wherein the control processor determines, from a signal from the sensor, concentration of CO₂ in a patient's end tidal breath.
24. (Withdrawn) The gas modulation system as claimed in Claim 17 wherein the control processor controls concentration of CO₂ for a patient diagnosed as having sleep disordered breathing (SDB).

25. (Withdrawn) The gas modulation system as claimed in Claim 24 wherein the patient has further been diagnosed as having Cheyne-Stokes respiration.
26. (Withdrawn) The gas modulation system as claimed in Claim 17 wherein the control processor controls concentration of CO₂ for a patient diagnosed as having an "Apparent Life Threatening Experience" (ALTE).
27. (Withdrawn) The gas modulation system as claimed in Claim 17 wherein the control processor controls concentration of CO₂ for a patient being diagnosed as having apnea of prematurity.
28. (Withdrawn) The gas modulation system as claimed in Claim 14 wherein the source of the first gas is a pressurized source; and
the gas modulation system further comprises a control valve module which regulates flow of the first gas from the pressurized source to the mixing means, the control valve module responding to a control signal from the control processor.
29. (Withdrawn) The gas modulation system as claimed in Claim 28, the control valve module comprising a solenoid valve.
30. (Withdrawn) The gas modulation system as claimed in Claim 28, the control valve module comprising a proportional valve.
31. (Withdrawn) The gas modulation system as claimed in Claim 28 further comprising a limiting orifice placed in series with the control valve module.

32. (Withdrawn) The gas modulation system as claimed in Claim 14 wherein the mixing means is one of (a) a gas mixing module having an input plenum, an output plenum and a flow channel which connects the input plenum to the output plenum; and (b) a tube or other enclosure without an input or output plenum.
33. (Withdrawn) The gas modulation system as claimed in Claim 14 further comprising any combination of:
 - (a) a flow meter which provides a visual or electrical indication of flow of the first gas into the mixing means; and
 - (b) an input flow sensor which measures flow of the first gas into the mixing means, the input flow sensor providing a signal to the control processor, the control processor controlling the concentration of the first gas in the gas mix responsive to said signal;
 - (c) a flow meter which provides a visual or electrical indication of flow of bleed air vented from the PCVSM; and
 - (d) a PCVSM exhaust air bleed sensor which measures flow of PCVSM exhaust bleed air, the PCVSM bleed air sensor providing a signal to the control processor, the control processor controlling the concentration of the first gas in the gas mix responsive to said signal.
34. (Withdrawn) The gas modulation system as claimed in Claim 14 further comprising:
a proportional valve which, responsive to a control signal from the control processor, regulates flow of bleed air vented from the PCVSM, the control processor dynamically controlling the proportional valve in response to detected system changes.

35. (Withdrawn) The gas modulation system as claimed in Claim 14 further comprising:
a manually operated valve which regulates flow of bleed air vented from the PCVSM.
36. (Withdrawn) The gas modulation system as claimed in Claim 14 wherein the control processor controls concentration of the first gas in the gas mix responsive to patient state information from any combination of: thermistors, strain gauges, skin conductance monitors, arterial contraction monitors, transcutaneous blood gas monitors and physiological signals.
37. (Withdrawn) The gas modulation system as claimed in Claim 36, wherein physiological signals include any of EEG signals, EKG signals, respiratory data or end tidal carbon dioxide signals.
38. (Withdrawn) The gas modulation system as claimed in Claim 14 further comprising:
a pneumotachograph mounted in proximity to the PCVSM, the pneumotachograph measuring inspired and expired breath volume and providing a pressure signal to the control processor, the control processor controlling the concentration of the first gas in the gas mix responsive to said signal.
39. (Withdrawn) The gas modulation system as claimed in Claim 14, further comprising:
a display monitor, connected to the control processor, the control processor displaying on the display monitor a scrolling chart recorder which displays at least one of:

CO₂ concentration, O₂ concentration, control processor control state, a sensor signal, and a physiological signal.

40. (Withdrawn) The gas modulation system as claimed in Claim 14, further comprising:
a remote interface to the control processor such that the control processor is controllable remotely from a remote workstation.
41. (Withdrawn) The gas modulation system as claimed in Claim 40, wherein the remote interface is a wired or wireless TCP/IP connection.
42. (Withdrawn) The gas modulation system as claimed in Claim 14, further comprising:
a gas sampling sensor which monitors concentration of at least the first gas within the mixing means, the gas sampling sensor providing a signal to the control processor, the control processor controlling the concentration of the first gas in the gas mix responsive to said signal.
43. (Withdrawn) The gas modulation system as claimed in Claim 42, wherein the gas sampling sensor monitors concentrations of carbon dioxide (CO₂) and oxygen (O₂).
44. (Withdrawn) The gas modulation system as claimed in Claim 14, wherein the control processor continuously receives and analyzes incoming data and indicates an alarm condition based on the incoming data and at least one of the following parameters:
maximum first gas flow;

maximum inspired first gas;
maximum arterial CO₂;
maximum end tidal carbon dioxide; and
maximum percent first gas in the mixing means,

the control processor stopping or reducing delivery of the first gas when an alarm condition is present.

45. (Withdrawn) The gas modulation system as claimed in Claim 44, the control processor sounding an audible alarm when an alarm condition is present.
46. (Withdrawn) The gas modulation system as claimed in Claim 14, wherein said system is adapted for use in a non-clinical setting, including any of:
 - (a) the source of the first gas being a canister having an orifice of size which limits maximum flow according to a specified limit;
 - (b) the system further comprising recording and reporting means;
 - (c) the recording and reporting means being remotely accessible; and
 - (d) the recording and reporting means being accessible via a dial-up connection.
47. (Withdrawn) A carbon dioxide (CO₂) based system for enabling respiratory stability, comprising:
 - a substantially leak-proof mask having an exhaust vent, said mask for use by a user;
 - a positive air pressure (PAP) module which delivers pressurized air to the mask;

a deadspace reservoir attached to the mask and retaining CO₂ expired by the user for subsequent re-inhalation by the user;

a sensor, located substantially at the mask, which measures concentration of carbon dioxide in the mask, said concentration dynamically changing as a function of the user's breathing; and

a control processor coupled to receive signals from the sensor, the control processor, based on the signals from the sensor, controlling the exhaust vent of the mask to control the level of carbon dioxide in the mask, such that levels of carbon dioxide for effecting respiratory stability are maintained in the mask and inhaled by the user.

48. (Withdrawn) The carbon dioxide based system of Claim 47, wherein the deadspace reservoir is formed by a length of hose.
49. (Withdrawn) The carbon dioxide based system of Claim 47, wherein the deadspace reservoir holds approximately 500 ml. of gas.
50. (Withdrawn) The carbon dioxide based system of Claim 47, wherein the exhaust vent includes one of: a proportional valve controllable by the central processor, a user controllable needle valve, and a variable orifice.
51. (Withdrawn) The carbon dioxide based system of Claim 47 wherein levels of below about 2% CO₂ are maintained in the mask.
52. (Withdrawn) The carbon dioxide based system of Claim 47 wherein levels of between about .5% and 1.25% of CO₂ are maintained in the mask.

53. (Withdrawn) A method for regulating carbon dioxide (CO₂) about a patient, comprising:
- providing a substantially leak-proof mask having (i) an exhaust vent and (ii) a deadspace reservoir for retaining a patient's expired CO₂ for subsequent re-inhalation by the patient, said mask being worn by the patient;
- supplying pressurized air to the mask;
- using computer means, measuring concentration of carbon dioxide in the mask, said concentration dynamically changing as a function of the patient's breathing; and
- based on measured concentration, controlling the concentration of carbon dioxide in the mask, and hence the concentration of CO₂ inhaled by the patient.
54. (Withdrawn) The method of Claim 53, wherein the deadspace reservoir comprises a length of hose.
55. (Withdrawn) The method of Claim 53, wherein the deadspace reservoir holds approximately 500 ml. of gas.
56. (Withdrawn) The method of Claim 53, wherein the step of controlling includes using one of a proportional valve, a needle valve and a variable orifice in the exhaust vent.
57. (Withdrawn) The method of Claim 53 wherein the step of controlling includes maintaining concentration of carbon dioxide at a level just sufficient for effecting respiratory stability.

58. (Withdrawn) A method as claimed in Claim 57 wherein concentration of carbon dioxide is maintained below about 2%.
59. (Withdrawn) A method as claimed in Claim 57 wherein concentration of carbon dioxide is maintained between about .5% and about 1.25%.
60. (Withdrawn) A computer program product for regulating concentration of a first gas in a gas mix used in a patient centric ventilatory space module (PCVSM), the computer program product comprising a computer usable medium having computer readable code thereon, including program code which:
 - receives flow information of the first gas;
 - receives sampled concentration of at least the first gas in the gas mix;
 - receives concentration data of at least the first gas in a patient's inhaled and expired breath, said concentration data being measured substantially at the PCVSM; and
 - analyzes the flow of the first gas, gas mix concentration of the first gas and concentration of the first gas in a patient's inhaled and expired breath, and based on said analysis regulates concentration of the first gas in the gas mix.
61. (Withdrawn) A method of treating respiratory instability in a patient, comprising the steps of:
 - mixing effectively minimum concentrations of CO₂ with pressurized air to form a gas mix; and
 - delivering the gas mix to a patient to inhale.

62. (Withdrawn) The method as claimed in Claim 61 wherein the step of mixing employs about 2% CO₂.
63. (Withdrawn) The method as claimed in Claim 61 wherein the step of mixing employs between about .5% and 1.25% CO₂.
64. (Withdrawn) The method as claimed in Claim 61 wherein the step of mixing employs positive airway pressure.
65. (Withdrawn) The method as claimed in Claim 61 wherein the step of delivering includes temporarily ceasing delivery of the gas mix during periods of detected stable breathing by the patient.
66. (Withdrawn) The method as claimed in Claim 61 wherein the step of delivering is performed during times of detection of the patient being at a point in a breathing cycle where expired CO₂ levels are decreasing.
67. (Withdrawn) The method as claimed in Claim 66 wherein the step of delivering includes delivering over a relatively short period of time with respect to the breathing cycle.
68. (Withdrawn) The method as claimed in Claim 61 wherein the step of mixing is performed in a deadspace area of a mask worn by the patient, and source of CO₂ is the patient's expired breath; and further comprising the step of venting the mask to control concentration of the CO₂.

69. (New) A device for stabilizing breathing comprising
a source of medical grade carbon dioxide;
an assembly for combining pressurized air from a positive airway pressure PAP
device with substantially low concentrations of the medical grade carbon dioxide
resulting in a gas mix; and
a patient centric ventilatory space module (PCVSM) coupled to the assembly
providing the resulting gas mix for inhalation by a given target, said inhalation of
the gas mix effecting respiratory stability of said target.
70. (New) A device as claimed in Claim 69 wherein at least one of the source, the
assembly and the PCVSM is computer processor controlled to modulate
concentration of carbon dioxide in the gas mix.
71. (New) A device as claimed in Claim 70 wherein the computer processor
modulates concentration of CO₂ in the gas mix as a function of any combination
of sensed concentration of carbon dioxide in the PCVSM, sensed target state and
detected system changes.
72. (New) A device as claimed in Claim 70 wherein the computer processor
continuously receives and analyzes incoming data and indicates an alarm
condition based on the incoming data and at least one of the following
parameters:
maximum first gas flow;
maximum inspired first gas;
maximum arterial CO₂;
maximum end tidal carbon dioxide; and
maximum percent first gas in the mixing means,

the computer processor stopping or reducing delivery of the first gas when an alarm condition is present.

73. (New) A device as claimed in Claim 70 further comprising a sensor wherein the computer processor determines, from a signal from the sensor, concentration of CO₂ in a patient's end tidal breath.
74. (New) A device as claimed in Claim 70 wherein the computer processor controls concentration of CO₂ for a patient diagnosed as having sleep disordered breathing (SDB).
75. (New) A device as claimed in Claim 70 wherein the source of the carbon dioxide is a pressurized source; and
the gas modulation system further comprises a control value module which regulates flow of the carbon dioxide from the pressurized source to the assembly, the control valve module responding to a control signal from the computer processor.
76. (New) A device as claimed in Claim 75, the control valve module comprising a solenoid valve.
77. (New) A device as claimed in Claim 75, the control valve module comprising a proportional valve.